

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: August 3, 2007

Signature: Shawn P. Foley

(Shawn P. Foley)

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER TEVNH 3.3-103
INTERNATIONAL APPLICATION NO. PCT/GB03/02669		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/516,943
INTERNATIONAL FILING DATE 20 June 2003		PRIORITY DATE CLAIMED 22 February 2002
TITLE OF INVENTION PHARMACEUTICAL COMPOSITION		
APPLICANT(S) FOR DO/EO/US Austen John Woolfe, Alan Langford, Jacqueline Yvonne Allen, and Marc Clifford Elliot		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.		
2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.		
3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.		
4. <input type="checkbox"/> The US has been elected (Article 31).		
5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))		
a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> has been communicated by the International Bureau.		
c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).		
6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).		
a. <input type="checkbox"/> is attached hereto.		
b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).		
7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))		
a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> have been communicated by the International Bureau.		
c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.		
d. <input type="checkbox"/> have not been made and will not be made.		
8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).		
10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 to 20 below concern document(s) or information included:		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13. <input type="checkbox"/> A preliminary amendment.		
14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.		
15. <input type="checkbox"/> A substitute specification.		
16. <input type="checkbox"/> A power of attorney and/or change of address letter.		
17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.		
18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).		
19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/516,943	INTERNATIONAL APPLICATION NO. PCT/GB03/02669	ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-103
20. <input checked="" type="checkbox"/> Other items or information: Third Renewed Petition Under 37 CFR 1.47(a), Affidavit of Samantha C. Radley (12 pgs), Petition for Extension of Time (3 mo), Return Receipt Postcard		
The following fees have been submitted 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300		CALCULATIONS \$
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200		\$
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500		\$
TOTAL OF 21, 22 and 23 =		\$ 0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
- 100 =	/50 =	x \$250.00
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	0
Independent claims	- 3 =	0
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+
TOTAL OF ABOVE CALCULATIONS =		\$ 0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		
SUBTOTAL =		\$ 0.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$
TOTAL NATIONAL FEE =		\$ 0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$
		\$
TOTAL FEES ENCLOSED =		\$ 0.00
		Amount to be refunded: \$
		Amount to be charged \$

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- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit
Account No. 12-1095 . A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information
should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be
filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Shawn P. Foley
SIGNATURE

Shawn P. Foley
NAME

CUSTOMER NUMBER: 000530

33,071
REGISTRATION NUMBER

COPY

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Signature: Shawn P. Foley (Shawn P. Foley)

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COPY

PTO-1390 (Rev. 09-2006)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/516,943		INTERNATIONAL APPLICATION NO. PCT/GB03/02669		ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-103	
20. <input checked="" type="checkbox"/> Other items or information: Third Renewed Petition Under 37 CFR 1.47(a), Affidavit of Samantha C. Radley (12 pgs), Petition for Extension of Time (3 mo.) Return Receipt Postcard					
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300				\$	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200				\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500				\$	
TOTAL OF 21, 22 and 23 =				\$ 0.00	
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- 100 =	/50 =		x \$250.00	\$	
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x 50.00	0.00	
Independent claims	- 3 =	0	x 200.00	0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+		
TOTAL OF ABOVE CALCULATIONS =				\$ 0.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 0.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(l)).				\$	
TOTAL NATIONAL FEE =				\$ 0.00	
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				\$	
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				Amount to be refunded:	\$
				Amount to be charged	\$

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SEND ALL CORRESPONDENCE TO:

Shawn P. Foley
SIGNATURE

Shawn P. Foley
NAME

CUSTOMER NUMBER: 000530

33,071
REGISTRATION NUMBER

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVNHC 3.3-103	
Application Number 10/516,943		Filed November 17, 2005	
For PHARMACEUTICAL COMPOSITION			
Art Unit N/A		Examiner Not Yet Assigned	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ 1,020.00
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ _____
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.			
<input type="checkbox"/> A check in the amount of the fee is enclosed.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input checked="" type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 12-1095 . I have enclosed a duplicate copy of this sheet.			
I am the <input type="checkbox"/> applicant/inventor.			
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number 33,071			
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
08/08/2007 MKAYPA GH 00000046 121095 10516943		August 3, 2007	
Signature		Date	
1020.00 DA Shawn P. Foley		(908) 518-6346	
Typed or printed name		Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input type="checkbox"/> Total of 1 forms are submitted.			

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Signature: Shawn P. Foley (Shawn P. Foley)

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Dated: August 3, 2007

Signature:

Shawn P. Foley
(Shawn P. Foley)

Docket No.: TEVNHC 3.3-103
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of
Woolfe et al

Application No.: 10/516,943

International Appln. No.
PCT/GB03/02669

International Appln. Filing Date:
June 20, 2003

For: PHARMACEUTICAL COMPOSITION

Mail Stop PCT
Commissioner for Patents
Office of PCT Legal Administration
P.O. Box 1450
Alexandria, VA 22313-1450

THIRD RENEWED PETITION UNDER 37 CFR 1.47(a)

Dear Sir:

This is in response to the Decision on Renewed Petition under 37 CFR 1.47(a) dated March 5, 2007, dismissing the Renewed Petition without prejudice. It is respectfully requested, in light of the arguments and evidence set forth herein, that this Third Renewed Petition under 37 CFR 1.47(a) be granted.

By way of background, Applicant, Norton Healthcare Limited, through its prior counsel, Michael A. Steinberg, filed a Petition Under 37 CFR 1.47(a) on November 17, 2005, to accept the application without the signatures of two joint inventors, namely, Jacqueline Yvonne Allen and Mark Clifford Elliott. In a Decision on Petition mailed February 24, 2006, the petition was dismissed because it did not contain certain statements with respect to providing a complete copy of the application papers to inventor Allen and for failure to show the efforts made to contact inventor Elliott.

In the Renewed Petition filed June 26, 2006, Petitioner provided evidence detailing the efforts made to contact the non-signing inventor Allen.

In the decision mailed March 5, 2007, the Patent Office found that all requirements of 37 CFR 1.47(a) with respect to inventor Allen had been satisfied. With respect to inventor Elliott, however, the Decision states:

With respect to counsel's inability to find or reach Mr. Elliott, Petitioner now presents the affidavit of Samantha Claire Radley. Ms. Radley's affidavit states that she conducted an Internet search for "Mr. Elliot" without success. However, it is noted that the nonsigning inventor's name is identified as Mark Clifford *Elliott*, on the published international application for PCT/GB03/02669, with Mr. Elliott's last name containing two ts. Since Mr. Elliott's name was misspelled for the Internet search, a new Internet search must be conducted for Mark Clifford Elliott, as the inventor's name is correctly spelled.

* * *

Since attempts to locate inventor *Elliott* were insufficient, it can not be concluded that a "diligent effort" was made to locate the non-signing inventor and that Mr. Elliott is unavailable to sign the application. The action taken by petitioner is not sufficient to prove that a "diligent effort" was made to contact the nonsigning inventor. Under these circumstances, it cannot be concluded that Mr. Elliott is unavailable to sign the application.

In view of the above, with respect to co-inventor Elliott, the decision indicates that Applicant's prior efforts were not diligent because they were directed to another person, namely Mark Clifford *Elliot*; (not *Elliott*). The Attorney Advisor recommended in her Decision that the petitioner should pursue further efforts to show diligent attempts to locate Mr. Elliott. It is believed the present Renewed Petition and the evidence attached hereto serve to satisfy this requirement.

The attached Affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited, documents her own diligent efforts in an attempt to locate Mr. Elliott. Specifically,

she attempted to obtain information from a former colleague as well as Norton's Human Resources Department. She also contacted the United Kingdom Post Office to obtain a "redirection advice" for inventor Elliott. The affidavit further states that she conducted various internet searches to obtain the telephone number or any information relating to inventor Elliott. However, all of these attempts to locate Mr. Elliott failed.

In view of the foregoing, Applicant respectfully submits that the requirements set forth in the PTO's decision have now been satisfied as they relate to inventor Elliott. Since all other requirements had already been satisfied, it is respectfully requested that the present renewed petition be granted.

It is believed that no petition fee is due. However, if there are any fees due and owing, the PTO is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: August 3, 2007

Respectfully submitted,

By Shawn P. Foley
SHAWN P. FOLEY
Registration No.: 33,071
Under 37 CFR 1.34(a)
LERNER, DAVID, LITTENBERG, KRUMHOLZ
& MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

Filed on behalf of Norton Healthcare Limited

Deponent: S. C. Radley

First Affidavit of the Deponent

Date of Swearing: 24th July 2007

Exhibits: SR1-5

IN THE MATTER of United States Patent Application Number 10/516,943

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited (Norton) and I make this affidavit in support of Norton's United States patent application number 10/516,943 entitled "Pharmaceutical Composition". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 24 October 2006, I read the Affidavit of Simone Frankel sworn in this case 10 April 2006. I noted that the last known address for Mark Clifford Elliott was 40 Farleigh Road, Stoke Newington, London N16 7TH.
3. On, or about 24 October 2006, I asked a former colleague of Mark Clifford Elliott named Dr. John Man whether he knew of Mark Clifford Elliott's present whereabouts. Dr. Man did not know the whereabouts of Mark Clifford Elliott as he had had no contact with him since he left the employment of Norton.
4. On 22 November 2006, I contacted Jaz Ghick of Norton's Human Resources Department to ensure that the last known address Norton had for Mark Clifford Elliott had not been updated or changed from that present in Simone Frankel's affidavit. The address that the Human Resources Department had was 40 Farleigh Road, Stoke Newington, London N16 7TH. However a request for an employment reference had been made by SRG limited of Buckland House, Waterside Drive, Langley Business Park, Slough SL3 6EZ.
5. On 22 November 2006, I spoke to Glen Harris of SRG Limited who informed me that they had had no contact with Mark Clifford Elliott since February 2006 and that he was unable to divulge the contact details on their records under the United Kingdom Data protection Acts but he would attempt to pass a message to Mark Clifford Elliott. I asked him to ask Mark Clifford Elliott to contact me urgently and gave him my direct dial telephone number. A telephone note of this conversation is attached as exhibit "SR1" to this affidavit.

6. Later, on 22 November 2006, Glen Harris contacted me to inform me that he had attempted to ring two different contact telephone numbers for Mark Clifford Elliott but in both cases the lines were dead. He told me he had also attempted to send an email but the email was reported as failed to be delivered. He told me that he could not contact Mark Clifford Elliott. A telephone note of this conversation is attached as exhibit "SR2" to this affidavit.

7. On 22 November 2006, I contacted the United Kingdom Post Office customer services department. I enquired whether they had a redirection advice for Mark Clifford Elliott for his last known address: 40 Farleigh Road, Stoke Newington, London N16 7TH. I was informed that they did not have such a redirection advice. A telephone note of this conversation is attached as exhibit "SR3" to this affidavit.

8. On 21 May 2007, I interrogated an internet based website called The Phone Book which holds residential telephone numbers for residents in the United Kingdom for "M C Elliott in London". The web site returned no results. I present a printout of that search as exhibit "SR4".

9. On 21 May 2007, I interrogated an internet based website called Google.co.uk for "Mark Clifford Elliott". The web site returned no results for Mark Clifford Elliott. I present a printout of that search as exhibit "SR5".

Sworn at... 62-65 CHANCERY...
PLACE, LONDON WC2N...
LLP...
this ... 24th ... day of
... JULY ... 2007



Signature of Deponent making the Affidavit

Before me,

KIRSTEN JANET...
DUNLOP...
...
...
...



Signature of Authorised Witness

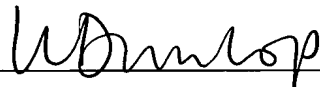
Shepherd and Wedderburn LLP
Condor House
10 St. Paul's Churchyard
LONDON
EC4M 8AL

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR1 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

Shepherd and Wedderburn LLP
Condor House
10 St. Paul's Churchyard
LONDON
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Note of Telephone Conversation between Samantha Radley and Glen Harris On 22 November 2006 at 14.30pm.

I asked Glen Harris if they had Mark Clifford Elliot on their records as, according to Norton Healthcare files, they had approached Norton for a reference for Mark Clifford Elliot in January 2005.

He confirmed that Mark Clifford Elliot was on their records but he was unable to divulge any contact details that they had because of the United Kingdom Data Protection Act.

He agreed to try and contact Mark Clifford Elliot on my behalf and pass on a message to him to contact me urgently on my direct dial telephone extension at Norton Healthcare Ltd.

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR2 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY


SAMANTHA CLAIRE RADLEY


PRACTISING SOLICITOR

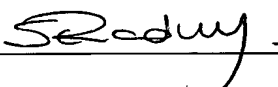
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Note of Telephone Conversation between Glen Harris and Samantha Radley On 22 November 2006 at 15.30pm.

Glen Harris told me that attempts to call Mark Clifford Elliot on the two telephone numbers that he had on his records were unsuccessful and an email that he had sent had been returned undeliverable.

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR3 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

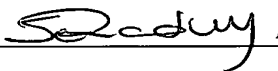
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Note of Telephone Conversation between Post Office Customer Services and
Samantha Radley on 22 November 2006 at 16.00pm.

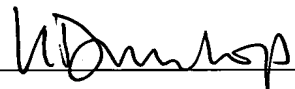
The Post Office Customer Services department confirmed that there was no
redirection address for Mark Clifford Elliot at 40 Farleigh Road, Stoke Newington,
London N16 7TH

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR4 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

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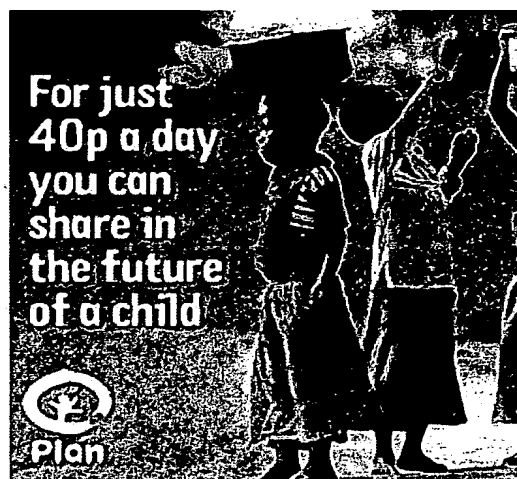
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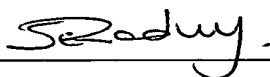
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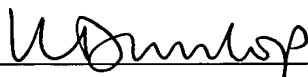
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IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR5 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



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